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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER
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ART UNIT	PAPER NUMBER
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DATE MAILED:

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/485,045

Applicant(s)

LEE ET AL.

Examiner

Janet L Andres

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 12-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 2-11 is/are rejected.
- 7) ☒ Claim(s) 3 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election of Group II, claims 2-11 in Paper No. 13 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The restriction requirement is still deemed proper and is therefore made FINAL.

### *Priority*

2. Applicant's priority claim to PCT/US98/15148, filed 24 July 1998, and provisional application 60/054606, filed 31 July 1997, is acknowledged.

### *Claim Objections*

3. Claim 3 is objected to because it refers to claimed sequence by reference to a figure number, rather than the identification number of an entered sequence. Correction is required.

### *Claim Rejections - 35 USC § 112*

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 2-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has described a sequence encoding a particular protein. However, the claims as written encompass any molecule that could be identified as encoding "GDF-16". Applicant has not set forth any particular structural features or structural

characteristics of "GDF-16" or described the conserved regions that would be critical for these features. Since these features are not disclosed, there is no way to determine what variations could be tolerated without altering them, or what fragments as claimed in claim 3, would possess the same defining characteristics. Further, the prior art does not provide compensatory structural or correlative teachings to enable one of skill to identify the polynucleotides encompassed: there is no basis by which "GDF-16" might be distinguished from other TGF- $\beta$  superfamily members. The art teaches closely related proteins: BMP-17 and BMP-18 (Celeste et al., U.S. patent 6027917) and TGF- $\beta$ 4 or endometrial bleeding associated factor (Tabibzadeh et al, GenBank Accession Number U81523, and U.S. Patent No. 5916751). Applicant has disclosed no features by which "GDF-16" could be distinguished from these. Therefore, applicant has not disclosed sufficient species or common structural features such that one skilled in the art would conclude that applicant was in possession of the claimed genus polynucleotides encoding "GDF-16".

6. Claims 2-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polynucleotide identified by SEQ ID NO:1, does not reasonably provide enablement for a genus identifiable as "GDF-16" or for fragments of the disclosed species. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant has described one polynucleotide. However, Applicant has not described the characteristics of this molecule that one of skill in the art could predictably identify other sequences encoding "GDF-16". Applicant has not described the properties or characteristics of the sequences that are required to encode a functional protein that is distinct from other members

of the superfamily. No conserved regions or regions, structures, or functions particular to "GDF-16" are described. Thus, the essential characteristics of nucleic acids encoding GDF-16 proteins are not described. Further, while recombinant techniques are available, it is not routine in the art to screen large numbers of nucleic acids that might potentially encode such proteins where the expectation of obtaining similar activity is unpredictable. Further, since the characteristic features of the claimed polynucleotide are not set forth, the skilled artisan would not be able to identify and use fragments of the polynucleotides, since there is no guidance for identifying those that would have such characteristic features. Thus one of skill in the art would require additional guidance, such as information as to what structural features would result the special characteristics of "GDF-16", in order to practice the invention commensurate with the scope of the claims without undue experimentation.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 2-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims identify the encoded protein as "GDF-16". The claims should refer to a sequence presented in the sequence listing. While the name itself may have some notion of the activity of the protein, there is nothing in the claim that distinctly identifies the protein or encoding nucleic acid. Others in the field may isolate the same protein and give it an entirely different name or give the same name to a different protein. Applicant should particularly point out definitive characteristics associated with the protein. Describing biochemical molecules by a particular name given to the protein by various workers in the field fails to distinctly identify

what the protein is. Thus "GDF-16" is not sufficient to identify the claimed invention; one of skill in the art would not be able to determine what molecules were encompassed.

9. Claim 3 is further indefinite in the recitation of "selectively hybridize". The definition on p. 7 is not sufficient because it does not point out what conditions or molecules are excluded; only examples are given. This claim is also indefinite in that it refers to Figure 1, rather than the identification number of an entered sequence, and because, as written, it identified a polynucleotide as a figure rather than as a molecule identified by a sequence.

**NO CLAIM IS ALLOWED.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 305-3014 or (703) 308-4242.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to **[yvonne.eyler@uspto.gov]**.

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly

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set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.

August 21, 2001

*Yvonne Eyer*  
YVONNE EYLER, PH.D.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600